

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**PLAINTIFFS' RESPONSE IN OPPOSITION TO MYLAN DEFENDANTS' MOTION  
TO DISMISS COUNTS ONE, TWO, AND THREE OF THE MASTER  
CONSOLIDATED COMPLAINT FOR INDIVIDUALS**

Plaintiffs, in opposition to the Defendants' Motion To Dismiss Counts One, Two, and Three of the Master Consolidated Complaint for Adoption by Individuals ("Master Complaint"), submit the following Memorandum.

**I. INTRODUCTION:**

In its motion, the Mylan Defendants seek dismissal of Counts One, Two, and Three of the Master Complaint. Said Counts allege product liability against the Mylan Defendants for failure to warn, manufacturing defect, and design defect, respectively.

Defendants seek dismissal of Count One due to a supposed failure to allege sufficient facts to establish the Mylan Defendants knew or had reason to know of the existence of a manufacturing defect prior to the recall of Digitek®. However, the Master Complaint more than satisfies the liberal notice pleading standards and alleges facts sufficient to state a claim against the Mylan Defendants for a failure to warn.

The Mylan Defendants further argue in regard to Count One that they cannot be liable for a failure to warn because there are no instructions or warnings that could have made Digitek® safe for consumers under the circumstances. Even assuming that fact to be true, the Mylan Defendants are not relieved from liability for failing to adequately warn the public.

In regard to Counts Two and Three the Mylan Defendants completely misstate the applicable law, arguing that as a distributor they cannot be held liable for defects in the manufacture or design of Digitek®. Inasmuch as it is well-established in the majority of jurisdictions that a distributor of a defective product bears liability for placing the product in the stream of commerce, the Mylan Defendants' motion must fail in regard to the Master Complaint.

**II. ARGUMENT:**

**A. Rule 12(b)(6) Standard:**

When ruling on a motion to dismiss, the Court must take as true the allegations of plaintiff's complaint. *See Brock & Davis Co. v. Charleston Nat'l Bank*, 443 F.Supp. 1175 (S.D.W.Va. 1977). A motion to dismiss may only be granted when the allegations pled in the complaint clearly demonstrate beyond doubt that the plaintiff has no claim, and that no set of facts would support plaintiff's claim. *See Conley v Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Booth v. Old Nat'l Bank*, 900 F.Supp. 836 (N.D.W.Va. 1995). Dismissal is justified only when the allegations of the complaint itself clearly show that the plaintiff does not have a claim. *See Cromer v. Lounsbury Chiropractic Offices, Inc.*, 866 F.Supp. 960 (S.D.W.Va. 1994) (citing 5A Wright, Miller & Cooper, *Federal Practice & Procedure* § 1357 344-345 (2d ed. 1990)).

**B. Count One of the Master Complaint is sufficiently pled.**

The Mylan Defendants' motion is without merit and should be denied. The Master Complaint is adequately pled. Federal Rule of Civil Procedure 8(a)(2) requires merely that a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Nowhere in the Rule does it state that a pleading must set forth facts. *See Jamison v. Olga Coal Co.*, 335 F.Supp. 454, 465 (S.D.W.Va. 1971). Where supporting facts have not been

pled, they may be secured by way of discovery. *See id.*; *Wilson v. Brown & Williamson Tobacco Corp.*, 968 F.Supp. 296 (S.D.W.Va. 1997) (allegations that defendant used additives to adulterate products resulting in a “flawed condition” sufficient). Rule 8 requires only a short and plain statement of a claim and the grounds upon which it rests, and need only contain sufficient factual detail to show that the claim is plausible rather than speculative. *Tamayo v. Blagojevich*, 526 F.3d 1074, 1081–83 (7th Cir. 2008) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).

Notwithstanding the fact that plaintiffs are not required to plead facts in their complaint, the Master Complaint alleges specific factual allegations regarding Mylan Defendants’ knowledge of the defect and their failure to act in regard to their knowledge. The Mylan Defendants are alleged to have been involved in multiple cases of adverse drug events, and the drug was the subject of multiple advisory letters from the FDA received by said defendants. (¶¶ 18-37.) The Master Complaint further alleges that the FDA initiated a recall of the product, which would have been directed, at least in part, to the Mylan Defendants. (¶ 38-53.)

The Mylan Defendants are further alleged to have failed to inform the medical community of the number and extent of injuries and other important information. (¶ 41-43.) It is specifically alleged that the Mylan Defendants knew that the product was unsafe and failed to inform the public of the reports of illnesses and injuries received (¶¶ 52, 53.)

Any one of these allegations alone is sufficient to provide enough factual information to satisfy the liberal notice pleading standard in regard to Count One. When aggregated, as they are in the Master Complaint, there can be no reasonable question as to the factual sufficiency of the allegations. The Mylan Defendants have been given more than adequate notice of the claims

asserted against them, as evidenced by the fact that they have articulated alleged defenses against them in their motion. As such, the Mylan Defendants' motion must be denied.

**B. The Master Complaint states a claim against the Mylan Defendants for a failure to warn.**

A product can be unreasonably dangerous if not accompanied by adequate warnings about its hazardous properties. *See Abbott v. American Cyanamid*, 844 F.2d 1108, 1115 (4<sup>th</sup> Cir. 1988); *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W.Va. 2007). With prescription drugs, the duty is to warn the physician administering the drug. *See Stanback v. Parke, Davis and Co.*, 657 F.2d 642, 644 (4<sup>th</sup> Cir. 1981). The issue, simply put, is whether the warning was reasonable, and the adequacy of the warning is a question of fact for the jury. *See Pfizer*, 272 S.E.2d at 44-45; *Wilkinson v. Duff*, 575 S.E.2d 335, 340-41 (W.Va. 2002).

Notably, the Mylan Defendants cite no cases in support of their novel proposition that liability for failure to warn exists only where a warning could make the product completely safe, or put another way, that no warning is required when the product is defective in manufacture or design. For obvious reasons, this is not the applicable test. The question is whether the Mylan Defendants provided an adequate warning in the face of the knowledge they possessed. That question cannot be properly answered without discovery, and as such, a motion to dismiss cannot be granted.

**C. Distributors bear liability for product liability claims for defective manufacture and design under the majority of state laws, and therefore, the Mylan Defendants' motion should be denied.**

Contrary to the way Mylan Defendants' argument makes it seem, distributors are not immune from liability for manufacture and design defects in all jurisdictions, or even in a majority of jurisdictions. *See e.g. Blankenship v. Ethicon*, 656 S.E.2d 451, 461 (W.Va. 2007) (“We made it clear in 1979 that the product liability principles established by *Morningstar* are

applicable to all manufacturers, **distributors**, suppliers and sellers of a defective product.” quoting *Morningstar v. Black and Decker Mfg. Co.*, 253 S.E.2d 666, 683 n.22 (W.Va. 1979)) (emphasis added); *Joseph v. Yenkin Majestic Paint Corp.*, 261 A.D.2d 512 (N.Y. App. Div. 1999) (quoting *Harrigan v. Super Prods. Corp.*, 237 A.D.2d 882 (N.Y. App. Div. 1997) and citing *Giuffrida v. Panasonic Indus. Co.*, 200 A.D.2d 713 (N.Y. App. Div. 1994)); *Duncan v. Cessna Aircraft Co.*, 665 S.W.2d 414, 432 (Tex. 1984); *Galindo v. Precision American Corp.*, 754 F.2d 1212, 1218 (5th Cir. 1985); *Waller v. Coca Cola Bottlers Association*, 523 S.W.2d 306 (Tex. App.—Houston 1975); *Oser v. Wal-Mart Stores, Inc.* 951 F.Supp. 115, 118–19 (S.D. Tex. 1996); *State Farm Ins. Companies v. Premier Manufactured Systems, Inc.*, 142 P.3d 1232, 1235 (Ariz. Ct. App. 2006).

The complaint at issue is the Master Complaint, the purpose of which is to set forth all potential claims within the scope of the MDL. See e.g., *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D.La. 2006) (“[A] master complaint is only an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint.”) (quoting *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 140-141 (E.D.La. 2002); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F.Supp.2d 932, 936 (D.C.Minn. 2007) (“Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits.”) Clearly, many plaintiffs encompassed by the Master Complaint have claims against the Mylan Defendants as distributors of a defective product even if those claims are not available to all plaintiffs. As such, the motion is without merit and should be denied.

**III. CONCLUSION:**

The Master Complaint states sufficient facts to satisfy the liberal notice pleading standards of Rule 8. Further, the Mylan Defendants' novel interpretation of the law of failure to warn is erroneous. Finally, the claims asserted against the Mylan Defendants as distributors of a product defective in manufacture and/or design are claims that may be pursued by the majority of Plaintiffs covered by the Master Complaint.

In light of all of the foregoing, and for the reasons set forth herein, the Mylan Defendants' motion should be denied.

WHEREFORE, the Plaintiffs pray that this Honorable Court deny the Mylan Defendants' motion to dismiss Counts One, Two, and Three of the Master Complaint, allow this matter to proceed to discovery, and grant such other and further relief as the Court deems meet and proper.

Dated: May 19, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 19, 2009, I electronically filed the foregoing "Response in Opposition to Defendants' Motion to Dismiss Count Eighteen of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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